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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,625	04/16/2001	Bruce J. Roser	263742000201	7829

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/05/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,625

Applicant(s)

ROSER ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,50 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,50 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claim 51 and adds new claims 53-54, which are related to claims 48, 50-52.

Accordingly, claims 48, 50, 52-54 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 48, 50, 52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Claim 48 is drawn to a method for reducing aggregation during dehydration and rehydration of particulates in suspensions comprising adding to said suspension "at least 10%"(w/v) of trehalose and dehydrating the suspension.

The specification does not disclose a method for reducing aggregation during dehydration and rehydration of particulates in suspensions comprising adding to said suspension "at least 10%" (w/v) of trehalose and dehydrating the suspension. The specification does not disclose the specific percentage of "at least 10%".

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2. Claim 52 is drawn to a method for reducing aggregation during dehydration and rehydration of particulates in suspensions comprising adding to said suspension "at least" 30%(w/v) of trehalose and dehydrating the suspension.

The specification does not disclose a method for reducing aggregation during dehydration and rehydration of particulates in suspensions comprising adding to said suspension "at least" 30%(w/v) of trehalose and dehydrating the suspension.

3. Claim 53 is drawn to a method for reducing aggregation during dehydration and rehydration of aluminum hydroxide particulates in suspensions comprising adding to said suspension "at least" 15%(w/v) of trehalose and dehydrating the suspension.

The specification does not disclose a method for reducing aggregation during dehydration and rehydration of aluminum hydroxide particulates in suspensions comprising adding to said suspension "at least" 15%(w/v) of trehalose and dehydrating the suspension.

4. Claim 54 is drawn to a method for reducing aggregation during dehydration and rehydration of aluminum hydroxide particulates in suspensions comprising adding to said suspension "at least" 30%(w/v) of trehalose and dehydrating the suspension.

The specification does not disclose a method for reducing aggregation during dehydration and rehydration of aluminum hydroxide particulates in suspensions comprising adding to said suspension "at least" 30%(w/v) of trehalose and dehydrating the suspension.

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REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT, NEW

REJECTION

with issue
Claims 48, 50, 52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 48, 50, 52-54 are drawn to a method for "reducing" aggregation during dehydration and rehydration of particulates in suspension comprising adding to said suspension "at least 10%", 15% or 30% (w/v) of trehalose and dehydrating the suspension. The particulates are colloidal gold, polystyrene latex, or aluminum hydroxide.

It is noted that due to the language "reducing", claims 48, 50, 52-54 encompass a method for reducing aggregation of particulates in suspension that have been aggregated, before the addition of trehalose, comprising adding to said suspension "at least 10%", 15% or 30% (w/v) of trehalose and dehydrating the suspension..

The specification discloses that while 15% and 30% trehalose present in the aluminum hydroxide sample during drying can prevent aggregation of aluminum hydroxide, 7.5% trehalose is insufficient to prevent said aggregation (p.12-13, and table 1 on page 12).

One cannot extrapolate the teaching of the specification to the enablement of the claims. It is unpredictable that the claimed 15% or 30% trehalose could "reduce" aggregation of particulates in suspension, which had been aggregated before the

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addition of trehalose, because it is unpredictable that trehalose could break up aggregates of particulates in suspensions. It is well known in the art that trehalose acts as a water radical scavenger, especially the OH species which are important in the aggregation processes of proteins, and saving the proteins from being attacked and denatured by the water-active species (Yousri, RM, 1980, Z. Ernährungswiss, 19(2): 111-121, especially page 116, last paragraph bridging page 117), IDS # 56 of paper No:8, on 09/12/02, and thus it is not clear how and at what concentration, trehalose could break up particulates that had been already aggregated. The specification however, only discloses that the presence of 15% or 30% of trehalose in the composition comprising the particulates in suspension during drying and rehydration could "prevent" aggregation of aluminum hydroxide.

Further, it is unpredictable that 10% of trehalose in claims 48 and 50 is sufficient to prevent aggregation of particulates, in view of the disclosure in the specification that 7.5% trehalose is insufficient to prevent said aggregation, i.e. not any concentration of trehalose is sufficient for preventing aggregation of particulates,

In view of the above, it would have been undue experimentation for one of skill in the art to practice the claimed invention as broadly as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

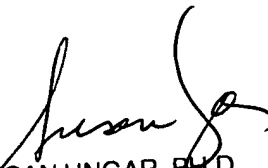
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

April 29, 2003


SUSAN UNGAR, PH.D
PRIMARY EXAMINER